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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,407	05/30/2001	Douglas J. LaCount	875.030US1	7075

21186 7590 07/15/2003

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/870,407

Applicant(s)

LACOUNT ET AL.

Examiner

Gerald G Leffers Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 30-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-29) in Paper No. 14, filed 4/28/03, is acknowledged. The traversal is on the ground(s) that 1) restriction is optional and 2) there would be no serious search burden placed on the examiner to search all of the claims of the different groups together because all of the claims feature dsRNA expression vectors. This is not found persuasive because of the following reasons.

Restriction is optional, so long as the inventions can be shown to be distinct from one another and so long as the examiner can demonstrate a serious search burden in examining the inventions of the different groups. The examiner provided a clear explanation as to why the different groups are different and distinct from one another in making the restriction requirement and also demonstrated that a search of the different inventions would be a serious burden by showing a different classification for each of the different inventions. A showing of a different classification for the different inventions is all that need be demonstrated in order to establish a burdensome search requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claims 30-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 14.

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Information Disclosure Statement

Receipt is acknowledged of an information disclosure statement, filed 5/30/01 as part of the application papers (Paper No. 1). The signed and initialed PTO Form 1449 has been mailed along with this action.

Drawings

Figure 2 of the originally filed application is a color photograph or drawing. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that it states in the preamble a double-stranded RNA (dsRNA) expression vector “effective” in a eukaryotic cell. It is unclear what structural/physical limitation is specified by the term “effective dsRNA”. This appears to be an inherently subjective term and does not appear to be clearly defined in the specification.

Claim 5 is vague and indefinite in that it is unclear the metes and bounds of the term “random DNA”. Does the term refer to a DNA synthesized in a purely random manner (e.g. not encoding any natural protein or transcript)? Or does the term mean that the DNA is unknown in the sense that its sequence is not known prior to its insertion into the dsRNA vector of the invention?

Claim 18 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term “the ribosomal RNA promoter”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5-6, 12-14 and 16-17, 19, 23-29 rejected under 35 U.S.C. 102(e) as being anticipated by Plaetinck et al (US 2003/0061626 A1; see the entire application).

Plaetinck et al teach screening methods for determining the function of a gene utilizing expression vectors capable of expressing dsRNAs (e.g. Abstract). The DNAs expressed as dsRNA are obtained from cDNA or genomic libraries and can be known or unknown (e.g. Abstract; page 1 paragraph 0004). Expressions used in the methods taught by Plaetinck et al can have promoters arranged head to head where the promoter is of the same type (e.g. Figure 8, two T7 promoters) or of different type (e.g. Figure 15, T7/T3/Sp6 promoters). Plant cells and *C. elegans* cells are two types of cells that can be used in the methods taught by Plaetinck et al (e.g. page 2, paragraph 0015). The vector can be a vector for integration into the host cell genome (e.g. Figure 8, "RNAi integration vector").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 8-10, 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plaetinck et al (US 2003/0061626 A1; see the entire document) in view of Ngo et al (applicants' submission as part of the IDS submitted with the application papers; PNAS USA, Vol. 95, pages 14687-14692, December 1998; see the entire reference).

The teachings of Plaetinck et al are described above and are applied as before, except:

Plaetinck et al do not teach the use of their system in protozoan cells to target essential genes.

Ngo et al teach the discovery that dsRNA induces mRNA degradation in *Trypanosoma brucei* (Abstract). The Ngo et al reference teaches that expression of the essential gene for α -tubulin results in the formation of multinucleate cells and a specific block of cytokinesis followed by cell death (e.g. Abstract). Ngo et al specifically teach that the effect they've characterized is not limited to α -tubulin mRNA but is applicable to other cellular RNAs and can be a powerful tool for genetically manipulating trypanosomes (e.g. Abstract). Ngo et al teach expression vectors that are dependent upon a head to head arrangement of repeat sequences (e.g. Figure 1). Ngo et al teach it is desirable to construct expression vectors that allow inducible expression of the dsRNAs (e.g. page 1496, column 1, last paragraph).

It would have been obvious to one of ordinary skill in the art at the time of applicants' invention to modify the techniques taught by Plaetinck et al for use in *Trypanosoma* as taught by Ngo et al because Plaetinck et al teach it is within the skill of the art to characterize the

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phenotype of a known or unknown gene in a host cell using expression vectors that express dsRNA and because Ngo et al teach that expression of dsRNA in *T. brucei* can result in the silencing of essential genes and that it is desirable to utilize dsRNA expression to characterize and genetically manipulate genes in *T. brucei*, an important human parasite. One would have been motivated to do so in order to receive the expected benefit of being able to inducibly express dsRNAs targeted to different genes in *T. brucei* in an inducible fashion in order to characterize their gene function. Absent evidence to the contrary, there would have been a reasonable expectation of success in using the constructs and methods taught by Plaetinck et al to characterize genes in *T. brucei* as taught by Ngo et al.


Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Gerald G Leffers Jr.
Examiner
Art Unit 1636

Ggl
July 14, 2003